UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	8

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/551,621	JIANG ET AL.	
	Examiner	Art Unit	
	Janet L. Epps	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-79 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 13-16, 35-38 and 40-43 drawn to a polypeptide, polypeptide compositions and fusion proteins, classified in class 530, subclass 350.

II. Claims 4-12, 17-20, 39, 44-47, and 77-79 are drawn to polynucleotides and polynucleotide compositions, classified in class 536, subclass 23.1.

III. Claims 21-22 are 72-76 drawn to an isolated antibody and antibody compositions, classified in class 530, subclass 387.1.

IV. Claims 23-28, drawn to antigen presenting cells and compositions comprising said cells, classified in class 435, subclass 325.

V. Claim 54, drawn to an isolated T cell population, classified in class 435, subclass 325.

VI. Claims 29, 34 and 48-49 drawn to a method for inhibiting the development of cancer in a patient comprising the administration of an effective amount of a polypeptide, classified in class 514, subclass 2. Claims 34 and 48-49 will be examined to the extent that it reads on administration of a polypeptide product.

VII. Claims 30, 34, and 48-49 drawn to a method for inhibiting the development of cancer in a patient, or breast cancer in a patient comprising the administration of an effective amount of a polynucleotide or a polynucleotide composition, classified in class 514, subclass 44. Claims

34 and 48-49 will be examined to the extent that it reads on administration of a polynucleotide product.

VIII. Claims 31 and 34 drawn to a method for inhibiting the development of cancer in a patient, or breast cancer in a patient comprising the administration of an antibody, classified in class 424, subclass 130.1. Claim 34 will be examined to the extent that it reads on administration of an antibody product.

IX. Claims 32-34, drawn to a method for inhibiting the development of a cancer in a patient, or breast cancer in a patient comprising the administering to a patient an effective amount of an antigen presenting cell, classified in class 424, subclass 93.1. Claim 34 will be examined to the extent that it reads on administration of an antigen-presenting cell.

X. Claims 50-52, drawn to a method for removing tumor cells from a biological sample comprising contacting a biological sample with T cells that specifically react with a breast tumor protein, and a method of administering said biological sample to a patient to inhibit the development of cancer, classified in class 424, subclass 93.1.

XI. Claim 53, drawn to a method for stimulating and/or expanding T cells specific for a breast tumor protein comprising contacting T-cells with a polypeptide, classified in class 514, subclass 2.

XII. Claim 53, drawn to a method for stimulating and/or expanding T cells specific for a breast tumor protein comprising contacting T-cells with a polynucleotide, classified in class 514, subclass 44.

XIII. Claim 53, drawn to a method for stimulating and/or expanding T cells specific for a breast tumor protein comprising contacting T-cells with a antigen presenting cell, classified in class 424, subclass 93.1.

XIV. Claim 55 drawn to a method of inhibiting the development of cancer in a patient comprising the administration of T-cells, classified in class 424, subclass 93.1.

XV. Claim 56-57 drawn to a method of inhibiting the development of a cancer in a patient comprising administering to the patient an effective amount of proliferated or cloned T-cells, classified in class 424, subclass 93.1.

XVI. Claims 58-61 drawn to a method for determining the presence or absence of a cancer or breast cancer in a patient comprising contacting a biological sample with an agent that binds a breast tumor protein, classified in 435, subclass 7.1.

XVII. Claims 62-65 drawn to a method for monitoring the progression of cancer in a patient comprising contacting a biological sample obtained from a patient with a binding agent that binds to a breast tumor protein, classified in 435, subclass 7.1.

XVIII. Claims 66-68 drawn to a method for determining the presence or absence of a cancer in a patient comprising contacting a biological sample obtained from a patient with an oligonucleotide, classified in 435, subclass 6.

XIX. Claims 69-71 drawn to a method for monitoring the progression of cancer in a patient comprising contacting a biological sample obtained from a patient with an oligonucleotide, classified in 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, III, IV, and V are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Database and the scientific literature would require the consideration of different patentability issues.

3. The methods of Groups VI-XIX differ in the method objectives, method steps, parameter, and/or in the reagents used. Due to the differences in the methods represented by the above groups, each group represents a patentably distinct invention.

4. Inventions of Group I and the Inventions of Group VI and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I can also be used in detection methods.

5. Inventions of Group II and the Inventions of Groups VII, XII and XVII-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group II can be used for the production of the polypeptide of Group I.

6. Inventions of Group III and the Inventions of Groups VIII, XIII and XVI-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group III can be used in a method of detection of the polypeptide of group I.

7. Inventions of Group IV and the inventions of Groups IX and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antigen presenting cells of Group IV can also be used in *in vitro* detection methods.

8. Inventions of Group V and the invention of Groups X, XIV-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T-cells of group XVI can also be used in *in vitro* diagnostic methods.

9. Groups I- XVII are drawn to polynucleotides and polypeptides encoded by said polynucleotides and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than ten individual, independent, and distinct nucleotide sequences in alternative form. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant's claimed sequences comprise open reading frames. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, in most cases, only one (1) independent and distinct nucleotide sequence will be examined in a single application without restriction. The search of no more than one sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences. Thus with the election of one of these groups, the applicant is required to selected one SEQ ID NO: from the group consisting of 2, 4-15, 18-33, 35-47, 49-56, 58, 63-73, 88-116, 141-159, 175, 178, 180, 185, 186, 194, 199, 205, 208, 211, 214-216, 219, 222, 226, 232, 236, 240, 241, 245-246, 252-268, 321-325, 343, 354, 367-369, 377,

382, 385, 389, 395, 397, 400, 408, 411, 413, 414, 416-417, 419-423, 426-427, 429, 431, 435-438, 441, 443-446, 450, 453-454, 463-468, and 474 for examination purposes.

10. Group I is drawn to polypeptides encoded by various SEQ ID NO:, or comprising an amino acid sequence defined by various SEQ ID NO:, cells expressing said polypeptides, and methods requiring the use of said polypeptides. Each polypeptide or antibody is a structurally and functionally different product and the examination of more than one sequence would result in an undue search burden on the PTO. Thus, with the election of Group I, the applicant is required to select one polypeptide or polypeptide encoding sequence from the group consisting of SEQ ID NO: 2, 4-15, 18-33, 35-47, 49-56, 58, 63-73, 88-116, 141-159, 175-176, 178-179, 180, 181, 185, 186, 194, 199, 205, 208, 211, 214-216, 219, 222, 226, 232, 236, 240, 241, 245-246, 252-268, 321-325, 343, 354, 367-369, 377, 382, 385, 389, 395, 397, 400, 408, 411, 413, 414, 416-417, 419-423, 426-427, 429, 431, 435-438, 441, 443-446, 450, 453-454, 463-468, 469-474, and 475 for examination purposes.

11. Because all inventions listed above are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

Janet L. Epps
Patent Examiner
June 21, 2001